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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,181	11/10/2000	Steven D. Jensen	7678.350.2	4245

22913 7590 04/05/2005

WORKMAN NYDEGGER
(F/K/A WORKMAN NYDEGGER & SEELEY)
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UT 84111

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,181

Applicant(s)

JENSEN ET AL

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41, 42 and 44-90 is/are pending in the application.
- 4a) Of the above claim(s) 89 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 42 and 44-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 12/15/04, with respect to the rejection(s) of claim(s) under 35 USC 102(b) and Obviousness-type Double Patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of arguments below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41,42,44-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (US 5,985,249; 11/16/99) on record. Fischer teaches a composition comprising 3-30 % peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10 % potassium nitrate. The composition can further comprise 0.5-20 % carboxypolymethylene, 20-85% polyol such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. See abstract, column 1 lines 25-34, column 3 line 58 – column 4 line 16, column 5 line 60 – column 9 line 45. Fischer's prior art invention discloses amounts of potassium nitrate (0.1-10 %) and peroxide (3-30 %), which encompass instant amounts of potassium nitrate and peroxide. For this reason, it would have been obvious to one having ordinary skill in the art at the time the prior art invention was made to employ the

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instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the prior art amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to non-working examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, Examiner argues that Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41,42,44-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,11,13-26 of U.S. Patent No. 6309625. Although the conflicting claims are not identical, they are not patentably distinct from each other because Fischer claims (USPN 6309625) a composition comprising peroxides such as carbamide peroxide and hydrogen peroxide

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plus 0.1-50 % potassium nitrate. The composition can further comprise 0.5-20 % carboxypolymethylene, 20-85% polyol such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Applicant's specification (USPN 6309625) teaches that the amount of peroxide ranges from 0.5-50 %. See column 9 lines 40-54. Fischer's invention (USPN 6309625) also claims a method to bleaching teeth with the composition with the aid of a tray. Fischer's invention (USPN 6309625) discloses amounts of potassium nitrate (0.1-50 %) and peroxide (0.5-50 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6309625) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the prior art invention was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6309625 amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to non-working examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, Examiner argues that Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%.

Claims 41,42,44-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306307. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because Fischer (USPN 6306307) claims a composition comprising 3-20 % peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10 % potassium nitrate. The composition can further comprise carboxypolymethylene, polyols such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Fischer's invention (USPN 6306307) also claims a method to whitening (bleaching) teeth with the composition with the aid of a tray. Fischer's invention (USPN 6306307) discloses amounts of potassium nitrate (0.1-10 %) and peroxide (3-20 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6306307) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the invention (USPN 6306307) was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6306307 amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to non-working examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, Examiner argues that Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%.

Election by Original Presentation

Newly submitted claims 88-90 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New claims are to a method of manufacturing a composition which are not originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 88-90 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is positioned above the printed name.

Alton Pryor
Primary Examiner
AU 1616